DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: LUSEDRA
Patent Nos. 6,204,257 and 6,872,838
Docket Nos.: FDA-2009-E-0202
FDA-2009-E-0204

MAR 24 2010

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,204,257 and 6,872,838, filed by University of Kansas, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for LUSEDRA (fospropofol disodium), the human drug product claimed by the patent.

The total length of the regulatory review period for LUSEDRA (fospropofol disodium) is 2,405 days. Of this time, 1,962 days occurred during the testing phase and 443 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: May 15, 2002.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 2002.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 27, 2007.

   FDA has verified the applicant's claim that the new drug application (NDA) 22-244 was submitted on September 27, 2007.

3. The date the application was approved: December 12, 2008.

   FDA has verified the applicant's claim that NDA 22-244 was approved on December 12, 2008.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Christopher N. Sipes
Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, DC 20004-2401